K062825

510(k) Summary
AOS Marker Seeds

MAY 22 2007

Alpha-Omega Services, Inc.
9156 Rose Street
Bellflower, CA 90706
Tel: (800) 346-7894
Fax: (562) 804-0604
Bob A. Robnett
July 2006

DEVICE NAME
AOS Marker Seeds

PROPRIETARY NAME
AOS Marker Seeds

COMMON/USUAL NAME
Marker Seeds

CLASSIFICATION
21 CFR 892.5700, Product Code: JAQ, Class II

PREDICATED DEVICES
AOS Marker Seeds (Preamendment, See Appendix A)

DESCRIPTION
AOS Marker Seeds are small, cylindrical pieces of 24k gold or silver, which are easily visible with radiography imaging systems.

INTENDED USE
AOS Marker Seeds are used to provide reference positions around a proposed treatment site in order to re-apply a radionuclide source into the body or to the surface of the body for multiple sessions of radiation therapy.

CONTRAINDICTIONS
Single Use Device

PERFORMANCE STANDARDS
No performance Standards for Brachytherapy Applicators are in effect at this date.

SUBSTANTIAL EQUIVALENCE

AOS Marker Seeds are substantial equivalence to the AOS Marker Seeds (Preamendment). A comparison summary of technological characteristics is listed below. See Sections 7 Device Description for detailed information.

NEW DEVICE:	AOS Marker Seeds, 24k Gold
PREDICATE:	AOS Marker Seeds, 24k Gold
DESIGN:	Both the new and predicate device share the same design
MATERIAL:	Both the new and predicate device are constructed of the same materials
SINGLE USE:	Both the new and predicate device are Single Use Only.
STERILE:	New device is sterile. Predicate is non-sterile

NEW DEVICE:	AOS Marker Seeds, 24k Silver
PREDICATE:	AOS Marker Seeds, 24k Silver
DESIGN:	Both the new and predicate device share the same design
MATERIAL:	Both the new and predicate device are constructed of the same materials
SINGLE USE:	Both the new and predicate device are Single Use Only.
STERILE:	New device is sterile. Predicate is non-sterile

Conclusions

The Conclusion drawn from the above is that the Marker Seeds are equivalent in safety and efficacy to their predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 22 2007

Mr. Bob A. Robnett
Director, Regulatory Affairs & Quality
Alpha-Omega Services, Inc.
9156 Rose Street
P.O. Box 789
BELLFLOWER CA 90706

Re: K062825
Trade/Device Name: AOS Marker Seeds
Regulation Number: 21 CFR §892.5730
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: KXK
Dated: May 2, 2007
Received: May 3, 2007

Dear Mr. Robnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K062825

Device Name: AOS Marker Seeds

Indications For Use: AOS Marker Seeds are used to provide reference positions around a proposed treatment site in order to re-apply a radionuclide source into the body or to the surface of the body for multiple sessions of radiation therapy.

Alpha-Omega Services (AOS) Marker Seeds are small cylindrical pieces of 24k gold or silver, which are easily visible with radiography imaging systems.

Prescription Use: Yes ~~***AND/OR***~~ ***Over-The Counter Use:*** NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office or Device Evaluation

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062825